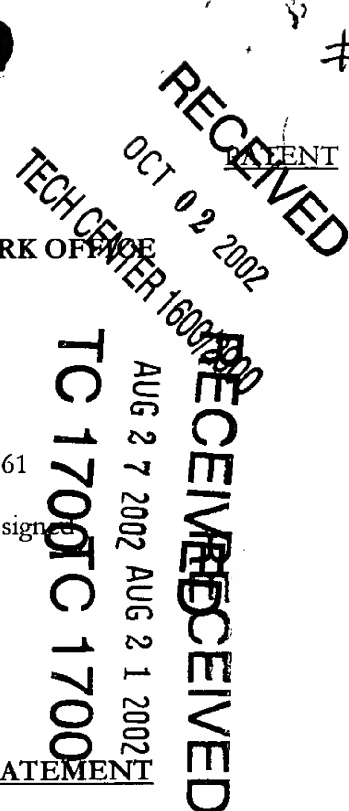


Docket No.: CI-0005



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Wilson BURGESS, William N. DROHAN,
Martin J. MACPHEE, David M. MANN
and Dawson BEALL

Serial No.: 09/960,705

Filed: September 24, 2001

For: A METHOD OF LYOPHYLIZATION
TO REDUCE SOLVENT CONTENT AND
ENHANCE PRODUCT RECOVERY

: Group Art Unit: 1761

: Examiner: To be assigned

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- ☒ 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart

foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).

a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

X 4. The relevancy of the non-English language reference(s) can be determined from the attached abstract(s).

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP



Mark L. Fleshner
Registration No. 34,596
Donald R. McPhail
Registration No. 35,811

Correspondence Address:
P.O. Box 221200
Chantilly, VA 20153-1200
Telephone: (703) 502-9440
Date: **August 26, 2002**

MLF/DRM:dbp

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

U.S. PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *ISSUE DATE | *INVENTOR NAME | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------|-------------|---------------------------|-------|----------|-------------|
| | A1 | RE 23,195 | 02/1950 | Arno Brasch | | | |
| | A2 | 2,832,689 | 04/1958 | Bernard E. Proctor et al. | | | |
| | A3 | 2,920,969 | 01/1960 | E.S. Stoddard | | | |
| | A4 | 2,962,380 | 11/1960 | J.H. Wertheim | | | |
| | A5 | 3,620,944 | 11/1971 | Keiko Tanito | | | |
| | A6 | 3,743,480 | 07/1973 | John D. Falk | | | |
| | A7 | 3,779,706 | 12/1973 | Nablo | | | |
| | A8 | 4,136,094 | 01/1979 | Condie | | | |
| | A9 | 4,251,437 | 02/1981 | Rasmussen et al. | | | |
| | A10 | 4,282,863 | 08/1981 | Beigler et al. | | | |
| | A11 | 4,330,626 | 05/1982 | Blair et al. | | | |
| | A12 | 4,370,264 | 01/1983 | Kotitschke et al. | | | |
| | A13 | 4,409,105 | 10/1983 | Hayashi et al. | | | |
| | A14 | 4,472,840 | 09/1984 | Jefferies | | | |

U.S. PATENT APPLICATION PUBLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT APPLN. PUB. NO. | *PUBLICATION DATE | *APPLICANT | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------------------|-------------------|------------|-------|----------|-------------|
| | B1 | | | | | | |

U.S. PATENT APPLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *APPLN. NO. | *FILING DATE | *INVENTOR | CLASS | SUBCLASS | |
|----------------------|----------|-------------|--------------|-----------|-------|----------|--|
| | C1 | | | | | | |

FOREIGN PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *PUBLICATION DATE | *COUNTRY | CLASS | SUBCLASS | Translation | |
|----------------------|----------|-------------|-------------------|-------------------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | D1 | 2,056,619 | 10/1991 | Canada | | | | |
| | D2 | 310 316 | 04/1989 | Europe | | | | |
| | D3 | 334 679 | 09/1989 | Europe | | | | |
| | D4 | 919 198 A2 | 06/1999 | Europe (Abstract) | | | X | |
| | D5 | 919 198 A3 | 06/1999 | Europe (Abstract) | | | X | |

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E1 | AABB FDA Liaison Meeting, ABC Newsletter, p. 14 (December 12, 1997) |
| | E2 | Alladine, M.F. et al., γ -Radiation Damage to Starr-Edwards Valves, The Lancet, 1:594 (1968) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

U.S. PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *ISSUE DATE | *INVENTOR NAME | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------|-------------|----------------------|-------|----------|-------------|
| | A15 | 4,620,908 | 11/1986 | Van Duzer | | | |
| | A16 | 4,784,850 | 11/1988 | Abraham | | | |
| | A17 | 4,798,611 | 01/1989 | Freeman Jr. | | | |
| | A18 | 4,865,602 | 09/1989 | Smestad et al. | | | |
| | A19 | 4,933,145 | 06/1990 | Uchida et al. | | | |
| | A20 | 4,946,648 | 08/1990 | Dichtelmüller et al. | | | |
| | A21 | 4,963,356 | 10/1990 | Calenoff et al. | | | |
| | A22 | 5,000,951 | 03/1991 | Bass et al. | | | |
| | A23 | 5,012,503 | 04/1991 | Nambu et al. | | | |
| | A24 | 5,106,619 | 04/1992 | Wieschahn et al. | | | |
| | A25 | 5,134,295 | 07/1992 | Wälischmiller | | | |

U.S. PATENT APPLICATION PUBLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT APPLN. PUB. NO. | *PUBLICATION DATE | *APPLICANT | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------------------|-------------------|------------|-------|----------|-------------|
| | B2 | | | | | | |

U.S. PATENT APPLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *APPLN. NO. | *FILING DATE | *INVENTOR | CLASS | SUBCLASS | |
|----------------------|----------|-------------|--------------|-----------|-------|----------|--|
| | C2 | | | | | | |

FOREIGN PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *PUBLICATION DATE | *COUNTRY | CLASS | SUBCLASS | Translation | |
|----------------------|----------|-------------|-------------------|-------------------------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | D6 | 11-216147 | 08/1999 | Japan (Abstract) | | | X | |
| | D7 | 1321420-A | 07/1987 | Soviet Union (Abstract) | | | X | |
| | D8 | WO 90/00907 | 02/1990 | PCT Int'l | | | | |
| | D9 | WO 91/16060 | 10/1991 | PCT Int'l | | | | |
| | D10 | WO 95/03071 | 02/1995 | PCT Int'l | | | | |

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E3 | Alper, T. et al., Protection by Anoxia of the Scrapie Agent and some DNA and RNA Viruses Irradiated as Dry Preparations, J. Gen. Virol., 3:157-166 (1968) |
| | E4 | Alper, T. et al., Does the Agent of Scrapie Replicate Without Nucleic Acid?, Nature, 214:764-766 (1967) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

RECEIVED
AUG 27 2002
TECH CENTER 1600/2900

U.S. PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *ISSUE DATE | *INVENTOR NAME | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------|-------------|-----------------|-------|----------|-------------|
| | A26 | 5,185,371 | 02/1993 | Rubinstein | | | |
| | A27 | 5,226,065 | 07/1993 | Held et al. | | | |
| | A28 | 5,283,034 | 02/1994 | Okrongly et al. | | | |
| | A29 | 5,362,442 | 11/1994 | Kent | | | |
| | A30 | 5,418,130 | 05/1995 | Platz. et al. | | | |
| | A31 | 5,460,962 | 10/1995 | Kemp | | | |
| | A32 | 5,510,122 | 04/1996 | Sreebny et al. | | | |
| | A33 | 5,548,066 | 08/1996 | Leneau et al. | | | |
| | A34 | 5,603,894 | 02/1997 | Aikus et al. | | | |
| | A35 | 5,609,864 | 03/1997 | Shanbrom | | | |
| | A36 | 5,637,451 | 06/1997 | Ben-Hur et al. | | | |
| | A37 | 5,643,464 | 07/1997 | Rhee et al. | | | |

U.S. PATENT APPLICATION PUBLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT APPLN. PUB. NO. | *PUBLICATION DATE | *APPLICANT | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------------------|-------------------|------------|-------|----------|-------------|
| | B3 | | | | | | |

U.S. PATENT APPLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *APPLN. NO. | *FILING DATE | *INVENTOR | CLASS | SUBCLASS | |
|----------------------|----------|-------------|--------------|-----------|-------|----------|--|
| | C3 | | | | | | |

FOREIGN PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *PUBLICATION DATE | *COUNTRY | CLASS | SUBCLASS | Translation | |
|----------------------|----------|---------------|-------------------|----------------------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | D11 | WO 00/25839 | 03/2000 | PCT Int'l (Abstract) | | | X | |
| | D12 | WO 01/08611A1 | 02/2001 | PCT Int'l (Abstract) | | | X | |
| | D13 | WO 01/12318A1 | 02/2001 | PCT Int'l | | | | |
| | D14 | WO 01/32107A2 | 05/2001 | PCT Int'l (Abstract) | | | X | |
| | D15 | WO 01/32110A2 | 05/2001 | PCT Int'l (Abstract) | | | X | |

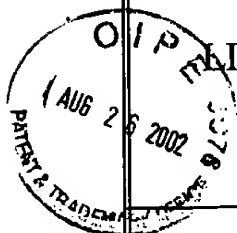
OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|--|
| | E5 | Alper, T. et al., The Exceptionally Small Size of the Scrapie Agent, Biochemical and Biophysical Research Communications, 22:278-284 (1966) |
| | E6 | Alper, T. et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, J. Gen. Virol., 41:503-516 (1978) |
| | E7 | Akkus, O. et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, J. Orthopaedic Research, 19:927-934 (2001) (Elsevier Science Ltd.) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1764

RECEIVED
 AUG 27 2002
 TC 1700

U.S. PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *ISSUE DATE | *INVENTOR NAME | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------|-------------|-----------------|-------|----------|-------------|
| | A38 | 5,712,086 | 01/1998 | Horowitz et al. | | | |
| | A39 | 5,730,933 | 03/1998 | Peterson | | | |
| | A40 | 5,817,528 | 10/1998 | Böhm et al. | | | |
| | A41 | 5,837,313 | 11/1998 | Ding et al. | | | |
| | A42 | 5,881,534 | 03/1999 | Ahlqvist et al. | | | |
| | A43 | 5,981,163 | 11/1999 | Horowitz et al. | | | |
| | A44 | 5,986,168 | 11/1999 | Noishiki | | | |
| | A45 | 5,989,498 | 11/1999 | Odland | | | |
| | A46 | 6,046,024 | 04/2000 | Burton et al. | | | |
| | A47 | 6,049,025 | 04/2000 | Stone et al. | | | |
| | A48 | 6,066,626 | 05/2000 | Yew et al. | | | |

RECEIVED
 OCT 02 2002
 TECH CENTER 1800/2000

U.S. PATENT APPLICATION PUBLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT APPLN. PUB. NO. | *PUBLICATION DATE | *APPLICANT | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------------------|-------------------|------------|-------|----------|-------------|
| | B4 | | | | | | |

U.S. PATENT APPLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *APPLN. NO. | *FILING DATE | *INVENTOR | CLASS | SUBCLASS | |
|----------------------|----------|-------------|--------------|-----------|-------|----------|--|
| | C4 | | | | | | |

FOREIGN PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *PUBLICATION DATE | *COUNTRY | CLASS | SUBCLASS | Translation | |
|----------------------|----------|---------------|-------------------|----------------------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | D16 | WO 01/45720A1 | 06/2001 | PCT Int'l (Abstract) | | | X | |
| | D17 | WO 01/49219A1 | 07/2001 | PCT Int'l | | | | |
| | D18 | WO 01/72233A1 | 10/2001 | PCT Int'l (Abstract) | | | X | |
| | D19 | WO 01/72244A1 | 10/2001 | PCT Int'l (Abstract) | | | X | |
| | D20 | WO 01/91818A1 | 12/2001 | PCT Int'l (Abstract) | | | X | |

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|--|
| | E8 | Aparicio, S.R. et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, J. Path., 115:147-162 (1975) |
| | E9 | Baksa, J. et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, Magyar Traumatologia, 19:138-145 (1976) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

U.S. PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *ISSUE DATE | *INVENTOR NAME | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------|-------------|-----------------------|-------|----------|-------------|
| | A49 | 6,087,141 | 07/2000 | Margolis-Nunno et al. | | | |
| | A50 | 6,120,592 | 09/2000 | Brault et al. | | | |
| | A51 | 6,159,490 | 12/2000 | Deghenghi | | | |
| | A52 | 6,171,549 | 01/2001 | Kent | | | |
| | A53 | 6,187,572 | 02/2001 | Platz et al. | | | |
| | A54 | 6,190,855 | 02/2001 | Herman et al. | | | |
| | A55 | 6,197,207 | 03/2001 | Chapman et al. | | | |
| | A56 | 6,203,544 | 03/2001 | Gotzen | | | |
| | A57 | 6,214,534 | 04/2001 | Horowitz et al. | | | |
| | A58 | 6,235,508 | 05/2001 | Sowemimo-Coker et al. | | | |

U.S. PATENT APPLICATION PUBLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT APPLN. PUB. NO. | *PUBLICATION DATE | *APPLICANT | CLASS | SUBCLASS | FILING DATE |
|----------------------|----------|-------------------------|-------------------|------------|-------|----------|-------------|
| | B5 | | | | | | |

U.S. PATENT APPLICATIONS

| *EXAMINER'S INITIALS | CITE NO. | *APPLN. NO. | *FILING DATE | *INVENTOR | CLASS | SUBCLASS | |
|----------------------|----------|-------------|--------------|-----------|-------|----------|--|
| | C5 | | | | | | |

FOREIGN PATENT DOCUMENTS

| *EXAMINER'S INITIALS | CITE NO. | *PATENT NO. | *PUBLICATION DATE | *COUNTRY | CLASS | SUBCLASS | Translation | |
|----------------------|----------|-------------|-------------------|----------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | D21 | | | | | | | |
| | D22 | | | | | | | |
| | D23 | | | | | | | |
| | D24 | | | | | | | |
| | D25 | | | | | | | |

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E10 | Baldwin, M.L. et al., Irradiation of Blood Components, pp. 10-78 (1992) (American Association of Blood Banks) |
| | E11 | Baquesy, C. et al., Radiosterilization of Albuminated Polyester Prostheses, Biomaterials, 8:185-189 (1987) |
| | E12 | Bassin, R.H. et al., Abrogation of Fv-1 ^b Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, Journal of Virology, 26:306-315 (1978) (American Society for Microbiology) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et a.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|--|
| | E13 | Beauregard, G. et al., Temperature Dependence of the Radiation Inactivation of Proteins, Analytical Biochemistry, 150:117-120 (1985) (Academic Press Inc.) |
| | E14 | Bedrossian Jr., E.H. et al., HIV and Banked Fascia Lata, Ophthalmic Plastic and Reconstructive Surgery, 7:284-288 (1991) (Raven Press Ltd.) |
| | E15 | Belov, A.A. et al., The Influence of γ -Radiation on Enzyme Activity of Collalitin in the Process of Storage, Radiobiologiia, 30:519-521(1990) |
| | E16 | Bingci, L., Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human Placenta Collagen, Chinese Medical Sciences Journal, 9:100-103 (1994) |
| | E17 | Blakeslee, S., Lack of Oversight in Tissue Donation Raising Concerns, The New York Times, Late Edition, pp. 1, 22 (January 20, 2002) |
| | E18 | Blanchy, B.B. et al., Immobilization of Factor VIII on Collagen Membranes, J. Biomedical Materials Research, 20:469-479 (1986) (John Wiley & Sons, Inc.) |
| | E19 | Block, S.S., Disinfection, Sterilization, and Preservation,, Fourth Edition, pp.31-33 (1991) (Lea & Febiger) (Philadelphia) |
| | E20 | Bogers, A.J.J.C. et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, Thorac. Cardiovasc. Surgeon, 42:337-339 (1994) (Georg Thieme Verlag Stuttgart) |
| | E21 | Borisova, E.A. et al., Protein Degradation During Interphase Death of Thymocytes Induced by Radation and Dexamethasone, pp.519-521 (1990) |
| | E22 | Boyer, T.D. et al., Radiation Inactivation of Microsomal Glutathione S-Transferase, The Journal of Biological Chemistry, 261:16963-16968 (1986) |
| | E23 | Brown, D.R. et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, J. Neurochem., 76:69-76 (2001) (Int'l Society for Neurochem.) |
| | E24 | Brown, P. et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, Transfusion, 38:810-816 (1998) |
| | E25 | Brown, P. et al., Effect of Chemicals, Heat and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, J. Infectious Diseases, 145:683-687 (1982) (University of Chicago) |
| | E26 | Brown, P. et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, Transfusion, 39:1169-1178 (1999) |
| | E27 | Brown, P., The Risk of Blood-Borne Creutzfeldt-Jakob Disease, Advances in Transfusion Safety Dev. Biol., 102:53-59 (1999) |
| | E28 | Burwell, R.G., The Fate of Freeze-Dried Bone Allografts, Transplantation Proceedings, 8(Suppl):95-111 (1976) |
| | E29 | Callegaro, L. et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, The International Journal of Artificial Organs, 6:91-96 (1983) (Wichtig Editore) |
| | E30 | Campalani, G. et al., Aortic Valve Replacement With Frozen Irradiated Homografts, Eur. J. Cardio-thorac. Surg., 3:558-561 (1989) (Springer-Verlag) |
| | E31 | Campbell, D.G. et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, Aust. N.Z. J. Surg., 69:517-521 (1999) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|-----------------|---|
| | E32 | Chanderkar, L.P. et al., The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation, Radiation Research, 65:283-291 (1976) (Academic Press, Inc.) |
| | E33 | Chanderkar, L.P. et al., Radiation-Induced Changes In Purified Prothrombin and Thrombin, Biochimica et Biophysica Acta, 706:1-8 (1982) (Elsevier Biomedical Press) |
| | E34 | Cheung, D. T. et al., The Effect of γ -Irradiation on Collagen Molecules, Isolated α -chains, and Crosslinked Native Fibers, J. Biomedical Materials Research, 24:581-589 (1990) (John Wiley & Sons, Inc.) |
| | E35 | Chin, S. et al., Virucidal Treatment of Blood Protein Products With UVC Radiation, Photochemistry and Photobiology, 65:432-435 (1997) (American Society for Photobiology) |
| | E36 | Chuchalin, A.G. et al., Clinical Immunosorbents Basing on Space-Network Polymers, Bioorg Khim, 14:1524-1529 (1988) (Russia) |
| | E37 | Cohen, D. J. et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, Chest, 93:482-484 (1988) |
| | E38 | Conrad, E. U. et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, J. Bone and Joint Surgery, 77-A:214-224 (1995) |
| | E39 | Cornu, O. et al., Effect of Freeze-Drying and Gamma Irradiation on the Mechanical Properties of Human Cancellous Bone, J. Orthopaedic Research, 18:426-431 (2000) |
| | E40 | Dagli, A. S., Correction of Saddle Nose Deformities by Coral Implantation, Eur. Arch. Otorhinolaryngol., 254:274-276 (1997) (Springer-Verlag) |
| | E41 | Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-Gamma-Ray, Radiat. Phys. Chem., 46:4-6 (Caplus Abstract No. 1995:923966) (1995) |
| | E42 | De Deyne, P. et al., Some Effects of Gamma Irradiation on Patellar Tendon Allografts, Connective Tissue Research, 27:51-62 (1991) (Gordon and Breach Science Publishers S. A.) |
| | E43 | Di Simplicio, P. et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, Free Rad. Res. Comm., 14:253-262 (1991) (Harwood Academic Publishers GmbH) |
| | E44 | Donnelly, R.J. et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, Thorax, 28:95-101 (1973) |
| | E45 | Dyskin, E.A. et al., Hemomicrocirculatory Bed in the Wall of Hollow Organs of the Dog Gastrointestinal Tract at Portal Hypertension, Arkh Anat Gistol Embiol, 93:58-68 (1987) |
| | E46 | Dziedzic-Goclawska, A. et al., Effect of Radiation Sterilization on the Osteoinductive Properties and the Rate of Remodeling of Bone Implants Preserved by Lyophilization and Deep-Freezing, Clinical Orthopaedics and Related Research, 272:30-37 (1991) |
| | E47 | Eichler, D.C. et al., Radiation Inactivation Analysis of Enzymes, J. Biological Chemistry, 262:9433-9436 (1987) |
| | E48 | Elliot, L.H. et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, J. Clinical Microbiology, 16:704-708 (1982) (American Society for Microbiology) |
| | E49 | Fideler, B. M. et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, American Journal of Sports Medicine, 23:643-646 (1995) |
| EXAMINER | DATE CONSIDERED | |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1784

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E50 | Fideler, B.M. et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, J. Bone and Joint Surgery, 76-A:1032-1035 (1994) (The Journal of Bone and Joint Surgery, Inc.) |
| | E51 | Fields, E.J. et al., Susceptibility of Scrapie Agent to Ionizing Radiation, Nature, 222:90-91 (1969) |
| | E52 | Ghosh, M.M. et al., A Comparison of Methodologies for the Preparation of Human Epidermal-Dermal Composites, Annals of Plastic Surgery, 39:390-404 (1997) (Lippincott-Raven Publishers) |
| | E53 | Gibbons, M.J. et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, J. Orthop Res., 9:209-218 (1991)(Orthopaedic Research Society) |
| | E54 | Gibbons, J.R.P. et al., Gamma Ray Sterilisation of Homograft Valves, Bulletin De La Societe Internationale De Chirurgie, 3:353-358 (1969) |
| | E55 | Goertzen, M.J. et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants, Knee Surg. Sports Traumatol. Arthroscopy, 2:150-157 (1994) (Springer-Verlag) |
| | E56 | Goertzen, M.J. et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon, J. Bone and Joint Surgery, 77-B:205-212 (1995) (British Editorial Society of Bone and Joint Surgery) (Retracted) |
| | E57 | Gregorczyk, S. et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur, Chir. Narz. Ruchu Ortop. Pol., 60:129-133 (1995) |
| | E58 | Guidoin, R. et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the Healing and Stability of Albuminated Polyester Grafts, Biomaterials, 6:122-128 (1985) (Butterworth & Co Ltd.) |
| | E59 | Haig, D.A. et al., Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, J. Gen. Virol, 5:455-457 (1969) |
| | E60 | Hehrlein, F. W. et al., Biochemical Changes in Heterologous Aortic Valve Transplants Following Application of Various Sterilization Methods, Langenbecks Arch Chair, 325:1183-1185 (1969) |
| | E61 | Hehrlein, F.W. et al., Morphological Studies on Heterologous Heart Valve Transplants Under Various Sterilization Conditions, Thoraxchir vask Chir, 17: 244-251(1969) |
| | E62 | Hernigou, P. et al., Radiation Sterilization of Bone and the HIV Virus, Revue de Chirurgie Orthopédique, 79:445-451 (1993) (Masson, Paris) |
| | E63 | Hiemstra, H. et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on Plasma and Coagulation Factors, Transfusion, 31:32-39 (1991) |
| | E64 | Hinton, R. et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia Lata Allografts, The American Journal of Sports Medicine, 20:607-612 (1992) (Am. Orthopaedic Soc. for Sports Medicine) |
| | E65 | Horowitz, B. et al., Inactivation of Viruses in a Labile Blood Derivatives, II. Physical Methods, Transfusion, 25:523-527 (1985) |
| | E66 | Horowitz, M., Sterilization of Homograft Ossicles by Gamma Radiation, J. Laryngology and Otology, 93:1087-1089 (1979) |
| | E67 | House, C. et al., Inactivation of Viral Agents in Bovine Serum by Gamma Irradiation, Can. J. Microbiol., 36:737-740 (1990) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E68 | Hsiue, G. et al., Absorbable Sandwich-Like Membrane for Retinal-Sheet Transplantation, pp.20-25 (2002) (Wiley Periodicals, Inc) |
| | E69 | Ijiri, S. et al., Effect of Sterilization on Bone Morphogenetic Protein, J. Orthopaedic Research, 12:628-636 (1994) (Orthopaedic Research Society) |
| | E70 | Imamaliyev, A.S. et al., Biological Properties of Bone Tissue Conserved in Plastic Material and Sterilized With Gamma Rays, ACTA Chirurgiae Plasticae, 16:129-135 (1974) (Avicenum, zdravotnické nakladatelství) |
| | E71 | Ingegneri, A. et al., An 11-Year Assessment of 93 Flash-frozen Homograft Valves in the Aortic Position, Thorac., Cardiovasc. Surgeon, 27:304-307 (1979) (Georg Thieme Verlag Stuttgart) |
| | E72 | Jensen, J. et al., Membrane-bound Na, K-ATPase: Target Size and Radiation Inactivation Size of Some of Its Enzymatic Reactions, J. Biological Chemistry, 263:18063-18070 (1988) (Am. Soc. for Biochem. and Mol. Biol.) |
| | E73 | Jensen, O. T. et al., Vertical Guided Bone-Graft Augmentation in a New Canine Mandibular Model, The Int'l Journal of Oral and Maxillofacial Implants, 10:335-343 (1995) |
| | E74 | Jerosch, J. et al., A New Technique for Bone Sterilization, Biomed. Technik, 34:117-120 (1989) |
| | E75 | Jerosch, J. et al., Influence of Different Rehydration Periods on the Stability and the Water Content of Bone Allografts After Lyophilization, Gamma-Irradiation, and Lipid Extraction, Z. Orthop., 132:335-341 (1994) (F. Enke Verlag Stuttgart) |
| | E76 | Kamat, H.N. et al., Correlation of Structural Alterations in Bovine Fibrinogen with Loss of Clotting Properties After Gamma Irradiation, Radiation Research, 49:381-389 (1972) (Academic Press, Inc.) |
| | E77 | Katz, R.W. et al., Radiation -Sterilized Insoluble Collagenous Bone Matrix is a Functional Carrier of Osteogenin for Bone Induction, Calcified Tissue Int., 47:183-185 (1990) (Springer-Verlag New York Inc.) |
| | E78 | Keathly, J.D. et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture, BioPharm, (July-August) pp. 46-52 (1993) |
| | E79 | Kempner, E.S. et al., Effect of Environmental Conditions on Radiation Target Size Analyses, Analytical Biochemistry, 216:451-455 (1994) |
| | E80 | Kempner, E.S. et al., Radiation-Damaged Tyrosinase Molecules are Inactive, Biophysical Journal, 55:159-162 (1989) (Biophysical Society) |
| | E81 | Kempner, E.S. et al., Size Determination of Enzymes by Radiation Inactivation, Analytical Biochemistry, 92:2-10 (1979) (Academic Press, Inc.) |
| | E82 | Kerboull, L. et al., In Vitro Study of the Influence of Various Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, Chirurgie, 117:751-762 (1991) (Masson, Paris) |
| | E83 | Kitchen, A.D. et al., Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, Vox Sang, 56:223-229 (1989) (S. Karger AG, Basel) |
| | E84 | Komender, A. et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, Archivum Immunologiae et Therapiae Experimentalis, 29:485-489 (1981) |
| | E85 | Komendar, A. et al., Some Biological Properties of Preserved Bovine Fascia Enriched With Pulverized Calf Cartilage, Archivum Immunologiae et Therapiae Experimentalis, 32:211-219 (1984) |
| EXAMINER | | DATE CONSIDERED |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E86 | Kouvalchouk, J.F. et al., The Use of Sterilized Bone Allografts in Reconstruction After Tumour Resection, <i>Revue de Chirurgie Orthopédique</i> , 72:393-401 (1986) (Masson, Paris) |
| | E87 | Kuijpers, A.J. et al., <i>In vivo</i> Compatibility and Degradation of Crosslinked Gelatin Gels Incorporated in Knitted Dacron, pp.137-144 (2000) (John Wiley & Sons, Inc.) |
| | E88 | Latarjet, R. Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by Radiations, <i>Slow Transmissible Diseases of the Nervous System</i> , 2:387-407 (1979) (Academic Press, Inc.) |
| | E89 | Latarjet, R. et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light, <i>Nature</i> , 227:1341-1343 (1970) |
| | E90 | Lee, D.C. et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, <i>Transfusion</i> , 41:449-455 (2001) |
| | E91 | Leitman, S. F. Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, <i>Transfus. Sci.</i> , 10:219-232 (1989) |
| | E92 | Le Maire, M. et al., Effects of Ionizing Radiations on Proteins, <i>Journal of Biochem.</i> , 267:431-439 (1990) |
| | E93 | License Amendment and Procedures for Gamma Irradiation of Blood Products, Dept. of Health & Human Services, Food and Drug Administration, pp. 1-18 (June 22, 1993) |
| | E94 | Linberg, J.V. et al., Preserved Irradiated Homologous Cartilage For Orbital Reconstruction, <i>Ophthalmic Surgery</i> , 11:457-462 (1980) |
| | E95 | Lüssi-Schlatter, B. et al., Antimicrobial Treatment of Enzyme Preparations With Gamma Rays, <i>Pharm Acta Helv.</i> , 49:66-75 (1974) |
| | E96 | McDowell, S., Irradiated Cartilage, <i>Plastic Surgical Nursing</i> , pp. 14-15 (Spring 1988) |
| | E97 | Ma, J.T. et al., Functional Size Analysis of F-ATPase from <i>Escherichia coli</i> by Radiation Inactivation, <i>The Journal of Biological Chemistry</i> , 268:10802-10807 (1993) (The Am. Soc. for Biochem. and Mol. Bio., Inc.) |
| | E98 | Maeda, A. et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Properties of Canine Tendon Allografts, <i>Journal of Orthopaedic Research</i> , 11:181-189 (1993) (Orthopaedic Research Society) |
| | E99 | Maeda, A. et al., Solvent-dried and Gamma-irradiated Tendon Allografts in Rats, <i>The Journal of Bone and Joint Surgery</i> , 80-B:731-736 (1998) |
| | E100 | Malawski, S. et al., The Use of Dry-Freezed Bone Grafts Sterilized by Gamma Rays in Orthopaedic Surgery, <i>Chir. Narz. Ruchu Ortop. Pol.</i> , 34:61-68 (1969) |
| | E101 | Malm, J. R. et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy, <i>J. Thoracic and Cardiovascular Surgery</i> , 54:471-477 (1967) |
| | E102 | Malm, J.R. et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, <i>Ann. N. Y. Acad. Sci.</i> , 147:740-747 (1969) |
| | E103 | Martindale, <i>The Extra Pharmacopoeia</i> , Glucose, Twenty-ninth Edition, Glucose, p. 1265 (1989) (The Royal Pharmaceutical Society of Great Britain) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|---|
| | E104 | Marton, L.S. et al., Disinfection and Inactivation of the Human T. Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus, The Journal of Infectious Diseases, 151:400-403 (1985) |
| | E105 | Marx, G. Protecting Fibrinogen with Rutin During UVC Irradiation for Viral Inactivation, Photochemistry and Photobiology, 63:541-546 (1996) (American Society for Photobiology) |
| | E106 | The Merck Index, Eleventh Edition, Glucose, pp. 699-700 (1989) (Merck & Co., Inc.) |
| | E107 | Miekka, S.I. et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, Haemophilia, 4:402-408 (1998) (Blackwell Science Ltd.) |
| | E108 | Moore, G.L. et al., Effects of 4000 Rad. Irradiation on the In Vitro Storage Properties of Packed Red Cells, Final Rept., Pub. in Transfusion, 25:583-585 (1985) (Abstract) |
| | E109 | Munting, E. et al., Effect of Sterilization on Osteoinduction, Acta Orthop. Scand., 59:34-38 (1988) |
| | E110 | Nagrani, S. et al., The Radiation-Induced Inactivation of External Yeast Invertase in Dilute Aqueous Solution, Int. J. Radiat. Biol., 55:191-200 (1989) (Taylor & Francis Ltd.) |
| | E111 | Nakata, K. et al, Reconstruction of the Lateral Ligaments of the Ankle Using Solvent-dried and Gamma-Irradiated Allogeneic Fascia Lata, The Journal of Bone & Joint Surgery, 82-B:579-582 (2000) (British Editorial Society of Bone and Joint Surgery) |
| | E112 | Nielsen, M. et al., The Apparent Target Size of Rat Brain Benzodiazepine Receptor, Acetylcholinesterase, and Pyruvate Kinase Is Highly Influenced by Experimental Conditions, The Journal of Biological Chemistry, 263:11900-11906 (1988) (The American Society for Biochemistry and Molecular Biology, Inc.) |
| | E113 | Oh, W. et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, J. Thoracic and Cardiovascular Surgery, 65:712-721 (1973) |
| | E114 | Pardo, M.E.M. et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis Bullosa, Annals of Transplantation, 4:68-73 (1999) |
| | E115 | Parizek, J. et al., Duraplasty With Pretreated Freeze-Dried Sterilized Human Dura Mater, Sbor. věd. Prací LF UK Hradec Králové., 33:135-143 (1990) |
| | E116 | Parizek, J. et al., Ovine Pericardium: A New Material For Duraplasty, J. Neurosurg, 84:508-513 (1996) |
| | E117 | Patel, K. M. et al., Effect of Gamma Radiation and Ethylene Oxide on Papain, Indian J. Pharm. Sci., 41:81-83 (1979) (The Indian Pharmaceutical Association) |
| | E118 | Pietrucha, K. et al., New Collagen Implant As Dural Substitute, Biomaterials, 12:320-323 (1991) (Butterworth-Heinemann Ltd.) |
| | E119 | Plavsic, Z. M. et al., Resistance of Porcine Circovirus to Gamma Irradiation, BioPharm, pp. 32-36 (April 2001) |
| | E120 | Polezhaev, L.V. et al., Repair of Cranial Defects With Regenerating Bone in Grafting Gamma-Irradiated Bone Filings, Zh Vopr Neifokhir Im N.N. Burdenko, (6):57-60 (1984) |
| | E121 | Pollard, The Effect of Ionizing Radiation on Viruses, pp. 65-7, Chapter 4 |
| | E122 | Potier, M. et al., Radiation Inactivation of Proteins: Temperature-Dependent Inter-Protomeric Energy Transfer in Ox Liver Catalase, Biochem. J., 298:571-574 (1994) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|--|
| | E123 | Prolo, D.J. et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemented With Fresh Iliac Corticocancellous Bone, Neurosurgery, 15:846-851 (1984) (The Congress of Neurological Surgeons) |
| | E124 | Prolo, D.J. et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical Sterilization, In Clinical Orthopaedics and Related Research; Section III: Basic Science and Pathology, (168):230-242 (1982) (J.B. Lippincott Co.) |
| | E125 | Puolakkainen, P.A. et al., The Effect of Sterilization on Transforming Growth Factor β Isolated From Demineralized Human Bone, Transfusion, 33:679-685 (1993) |
| | E126 | Quaglio, E. et al., Copper Converts the Cellular Prion Protein into a Protease-resistant Species That Is Distinct from the Scrapie Isoform, J. Biological Chemistry, 276:11432-11438 (2001) (The American Society for Biochemistry and Molecular Biology, Inc.) |
| | E127 | Raptopoulou-Gigi, M. et al., Antimicrobial Proteins in Sterilised Human Milk, British Medical Journal, 1:12-14 (1977) |
| | E128 | Rasmussen, T.J. et al., The Effects of 4 Mrad of γ Irradiation on the Initial Mechanical Properties of Bone-Patellar Tendon-Bone Grafts, Arthroscopy: J. Arthroscopic and Related Surgery, 10:188-197 (1994) (Raven Press, Ltd.) |
| | E129 | Reid, B.D., The Sterways Process: a New Approach to Inactivating Viruses Using Gamma Radiation, Biologicals, 26:125-130 (1998) (The Int'l Assoc. of Biological Standardization) |
| | E130 | Ripamonti, U. et al., Long-Term Evaluation of Bone Formation by Osteogenic Protein 1 in the Baboon and Relative Efficacy of Bone-Derived Bone Morphogenetic Proteins Delivered by Irradiated Xenogeneic Collagenous Matrices, J. Bone and Mineral Research, 15:1798-1809 (2000) (Am. Soc. for Bone and Mineral Res.) |
| | E131 | Rittenhouse, E. A. et al., Sterilization of Aortic Valve Grafts for Transplantation, Archives of Surgery, 101:1-5 (1970) |
| | E132 | Roe, S.C. et al., The Effect of Gamma Irradiation on Xenograft Tendon Bioprosthesis, Clinical Materials, 9:149-154 (1992) (Elsevier Science Publishers Ltd.) |
| | E133 | Rohwer, R.G., Estimation of Scrapie Nucleic Acid MW from Standard Curves for Virus Sensitivity to Ionizing Radiation, Nature, 320:381 (1986) (Macmillan Journals Ltd.) |
| | E134 | Rohwer, R.G., Scrapie Infectious Agent is Virus-like in Size and Susceptibility to Inactivation, Nature, 308:658-662 (1984) |
| | E135 | Rohwer, R.G., The Scrapie Agent: "A Virus by Any Other Name", Current Topics in Microbiology and Immunology, 172:195-232 (1991) |
| | E136 | Rohwer, R.G. et al., Scrapie-Virus or Viroid, The Case For a Virus, National Institutes of Neurological and Communicative Disorders and Stroke, NIH, pp. 333-355 (1980) |
| | E137 | Rohwer, R.G., Virus-Like Sensitivity of the Scrapie Agent to Heat Inactivation, Science, 223:600-602 (1984) (American Association for the Advancement of Science) |
| | E138 | Sakai, T. et al., Microbiological Studies on Drugs and Their Raw Materials. IV. Sterilization of Microbial Contaminants in Enzyme Powder by Gamma Irradiation, Chem. Pharm. Bull., 26:1130-1134 (1978) |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|--|
| | E139 | Salehpour, A. et al., Dose-Dependent Response of Gamma Irradiation on Mechanical Properties and Related Biochemical Composition of Goat Bone-Patellar Tendon-Bone Allografts, J. Orthopaedic Research, 13:898-906 (1995) |
| | E140 | Salim-Hanna, M. et al., Free Radical Scavenging Activity Of Carnosine, Free Rad. Res. Comms., 14:263-270 (1991) (Harwood Academic Publishers GmbH) |
| | E141 | Sato, H. et al., Sterilization of Therapeutic Immunoabsorbents by Ionizing Radiation, The International Journal of Artificial Organs, 9:131-136 (1986) |
| | E142 | Schwarz, N. et al., Irradiation-sterilization of Rat Bone Matrix Gelatin, Acta Orthop Scand, 59:165-167 (1988) |
| | E143 | Shcheglova, S.G. et al., The Effect of the Power of Gamma-Radiation on the Radiation dose in the Sterilization of Drugs, Khim Farm ZH, 18:730-732 (1984) Derwent (Abstract) No. 111469 |
| | E144 | Smith, C.W. et al., Mechanical Properties of Tendons: Changes With Sterilization and Preservation, J. Biomechanical Engineering, 118:56-61 (1996) (ASME) |
| | E145 | Smith, R.A. et al., Gamma Irradiation of HIV-1, J. Orthopaedic Research, 19:815-819 (2001) (Elsevier Science Ltd.) |
| | E146 | Song, K.B. et al., Effect of Gamma-irradiation on the Physicochemical Properties of Blood Plasma Proteins, 2002 Annual Meeting and Food Expo-Anaheim, California, Session 30C-1, Food and Chemistry: Proteins, (June 2002) (Abstract) |
| | E147 | Sullivan, R. et al., Inactivation of Thirty Viruses by Gamma Radiation, Applied Microbiology, 22:61-65 (1971) (American Society for Microbiology) |
| | E148 | Sung, H. et al., Effects of Various Chemical Sterilization Methods on the Crosslinking and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, Sterilization of Biological Tissues, J. Biomed. Mater. Res., 37:376-383 (1997) (John Wiley & Sons, Inc.) |
| | E149 | Suomela, H., Inactivation of Viruses in Blood and Plasma Products, Transfusion Medicine Reviews, 7:42-57 (1993) (W.B. Saunders Company) |
| | E150 | Toritsuka, Y. et al., Effect of Freeze-Drying or γ -Irradiation on Remodeling of Tendon Allograft in Rat Model, J. Orthopaedic Research, 15:294-300 (1997) (Orthopaedic Research Society) |
| | E151 | Tylman, D., Mechanical Character of Liofilized and Sterilized by γ -Rays Bone Tissue, Chirurgia Narzadow Ruchu I, Ortopedia Polska, 31:229-234 (1966) |
| | E152 | Vaida, R.I. et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs, Arkn. Anat. Gistol. Embriol., 8:68-73 (1987) |
| | E153 | Wangerin, K., et al., Behavior of Differently Sterilized Allogenic Lyophilized Cartilage Implants in Dogs, J. Oral Maxillofac Surg., 45:236-242 (1987) |
| | E154 | Welch, W., A Comparative Study of Different Methods of Processing Aortic Homografts, Thorax, 24:746-749 (1969) |
| | E155 | White, J.M. et al, Sterilization of Teeth by Gamma Radiation, J. Dent Res., 73:1560-1567 (1994) |
| | E156 | Wientroub, S. et al., Influence of Irradiation on the Osteoinductive Potential of Demineralized Bone Matrix, Calcified Tissue International, 42:255-260 (1988) (Springer-Verlag New York Inc.) |
| | E157 | Wong, B. et al., Copper Refolding of Prion Protein, Biochemical and Biophysical Research Communications, 276:1217-1224 (2000) (Academic Press) |
| EXAMINER | | DATE CONSIDERED |

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**LIST OF PRIOR ART CITED BY
APPLICANT
SUBSTITUTION FOR
(PTO-1449)**

ATTY. DOCKET NO.
CI-0005

APPLN. SERIAL NO.
09/960,705

APPLICANT
Wilson BURGESS et al.

FILING DATE
September 24, 2001

GROUP
1761

OTHER ART

RECEIVED
AUG 27 2002
TC 1700

| *EXAMINER'S INITIALS | CITE NO. | (AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION) |
|----------------------|----------|--|
| | E158 | Wong, B. et al., Differential Contribution of Superoxide Dismutase Activity by Prion Protein <i>in Vivo</i> , Biochemical and Biophysical Research Communications, 273:136-139 (2000) (Academic Press) |
| | E159 | Wong, B. et al., Prion Disease: A Loss of Antioxidant Function? Biochemical and Biophysical Research Communications, 275:249-252 (2000) (Academic Press) |
| | E160 | Wyatt, D.E. et al., Is there Life After Irradiation? Part I: Inactivation of Biological Contaminants, BioPharm, pp. 34-39 (June 1993) |
| | E161 | Yarygina, G.A., Dose Rate Effect on Survival of Microorganisms Used As Test-Cultures in Radiation Sterilization of Medical Products, 9:32-39 (1973) (Radiats Tekh) |
| | E162 | Zhang, Q. et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone, Acta Orthop Scand, 68:104-108 (1997) (Scandinavian University Press) |
| | E163 | Zhang, Y. et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, Spine, 19:304-308 (1994) (J.B. Lippincott Co.) |
| | E164 | (Abstract of EP0919198A2 and EP0919198A3 (Delphion-DERABS Abstract # G1999-304614)) |
| | E165 | Website: www.wslfweb.org/docs/dstp2000.dtopdf/19-MD.pdf (Defense Science and Technology Plans, (February 2000) p. 176, Section II, MD.03, U.S. Department of Defense Deputy Under Secretary of Defense (Science and Technology)) |
| | E166 | Website: www.usacc.org/ataccc/ppt.html , (Advanced Technology Applications for Combat Casualty Care, 2001 Presentations, US Army Medical Research and Materiel Command Combat Casualty Care Research Program (2001)) |
| | E167 | Website: www.usacc.org/RevisedStepB.html , Bakaltcheva, I. et al., (FY01 Request for Proposals-Intramural-Revised 2, Combat Casualty Care Research Program, (2002)) |
| | E168 | Website: www.benvue.com/history/history_content.html , (2002) |
| | E169 | |
| | E170 | |
| | E171 | |
| | E172 | |
| | E173 | |
| | E174 | |
| | E175 | |
| | E176 | |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.